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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/441,493	11/17/1999	JAMES MARTIN LENHARD	PU3571US	4399

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EXAMINER

ZEMAN, ROBERT A

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 09/10/2003

21

Please find below and/or attached an Office communication concerning this application or proceeding.

File Copy

Office Action Summary

Application No.

09/441,493

Applicant(s)

LENHARD ET AL.

Examiner

Robert A. Zeman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 July 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 18 and 24 is/are allowed.
- 6) ☒ Claim(s) 13-17, 19-23 and 25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

The amendment filed on 7-1-2003 is acknowledged. Claims 13-24 have been amended. Claims 1-8 have been canceled. Claim 25 has been added. Claims 13-25 are pending and currently under examination.

Drawings

The drawings were received on 7-1-2003. These drawings are acceptable. Said drawings have been forwarded to the Draftsman.

Claim Rejections Withdrawn

The rejection of claim 13 under 35 U.S.C. 112, second paragraph, as being rendered vague and indefinite by the use of the phrase “portion of skin sufficient to expose the internal organ” is withdrawn in light of the amendment thereto.

The rejection of claim 15 under 35 U.S.C. 112, second paragraph, as being rendered vague and indefinite by the use of the phrase “wherein one or more dosages of said test agent are sequentially administered and the temperature of the organ for each dose **is** determined” is withdrawn in light of the amendment thereto.

The rejection of claim 19 under 35 U.S.C. 112, second paragraph, as being rendered vague and indefinite by the use of the terms “relative temperature” and “relative temperature changes” is withdrawn in light of the amendment thereto.

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The rejection of claims 19-22 under 35 U.S.C. 112, second paragraph, as being rendered vague and indefinite by the use of the phrase “removing the mammalian skin overlaying the internal tissue or organ” is withdrawn in light of the amendment thereto.

The rejection of claim 21 under 35 U.S.C. 112, second paragraph, as being rendered vague and indefinite by the use of the phrase “the relative temperature change of the tissue or organ for each dose is monitored” is withdrawn in light of the amendment thereto.

The rejection of claim 21 under 35 U.S.C. 112, second paragraph, as being rendered vague and indefinite by the use of the phrase “one or more doses of the test agent are administered” is withdrawn in light of the amendment thereto.

Claim Rejections Maintained

35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 13-17, 19-23 and 25 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods of determining the temperature of (or the change in relative temperature in) internal tissues or organs comprising replacing a portion of skin sufficient to expose the internal organ or tissue with a infrared-invisible polymer and measuring said temperature using infrared thermography in **mice or rats**, does not reasonably

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provide enablement for methods of determining the temperature of (or the change in relative temperature in) internal tissues or organs comprising replacing a portion of skin sufficient to expose the internal organ or tissue with a infrared-invisible polymer and measuring said temperature using infrared thermography **in any other mammal other than mice or rats** for the reasons set forth in the previous Office action in the rejection of claims 13-17 and 19-23. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Applicant argues:

1. There are no real technological questions unanswered by the specification that would prevent one of skill in the art from practicing the claimed invention on other rodents or even other mammals.
2. Use of the present invention may require one of skill in the art to take into account the particular characteristics of the animal being studied.
3. In order to carry out the invention, different mammals may require different specific protocols depending on the animal and what tissue or organ is being investigated.
4. Based on the disclosure provided, one of skill in the art can adjust a given protocol to account for the particular characteristics of an animal.

Applicant's arguments have been fully considered and deemed non-persuasive.

As outlined previously, the specification provides examples of mice and rats having portions of their skin removed (peeled back) and replaced with an infrared-invisible polymer (see page 35, Example 22, Figure 26 and Figures 28-30). However, the specification provides no guidance as the area of skin that must be replaced relative to the size of the mammal, whether

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said area is dependent on the physical characteristics (i.e. size, percent body fat, presence of fur, etc.) of the mammal or the effect of bone, cartilage and muscle mass on infrared thermography.

Contrary to Applicant's assertion, the specification does not provide sufficient guidance to allow one of skill in the art to "adjust" the disclosed protocol for a given animal. The instant claims are drawn to **all mammals**, and as such include mammals ranging in size from a mouse to a whale.

The specification provides no guidance on how the claimed methodology can be applied to mammals larger than a mouse or a rat since it is silent on the effect adipose tissue; cartilage, muscle and bone have on the required "exposing" of the tissue or internal organ. Therefore, due to the lack of guidance within the specification, one of skill in the art would not be able to use the invention commensurate in scope with the claims.

Conclusion

Claims 18 and 24 are allowed.

Claims 13-17, 19-23 and 25 are rejected.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after

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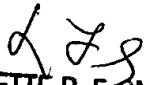
the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert A. Zeman whose telephone number is (703) 308-7991. The examiner can normally be reached on Monday- Thursday, 7am -5:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (703) 308-3909. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Robert A. Zeman
September 8, 2003


LYNETTE R. F. SMITH
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER